Docket No.: PD06063 US01

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (currently amended) A metered dose inhaler containing an aerosol suspension formulation for inhalation, said aerosol suspension formulation for inhalation comprising: an effective amount of mometasone furoate, a dry powder surfactant and HFA 227, wherein the formulation is ~~substantially~~ free of a carrier.

2. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 1, wherein the mometasone furoate is present in an amount of about 50 μg to about 400 μg.

3. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 2, wherein the mometasone furoate is present in an amount of about 100 μg.

4. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 2, wherein the mometasone furoate is present in an amount of about 200 μg.

5. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 2, wherein the mometasone furoate is present in an amount of about 400 μg.

6. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 1, wherein the dry powder surfactant is selected from the group consisting of lecithin, stearic acid, palmitic acid, magnesium stearate, magnesium palmitate, and magnesium laureate.

7. (original) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 1, wherein the formulation is free of additional excipients, and wherein the metered dose inhaler emits a dose having uniform drug content upon actuation of the metered dose inhaler.

8. (currently amended) The metered dose inhaler containing an aerosol suspension formulation for inhalation according to claim 1, wherein the percent of ~~the~~ fine particles dispensed upon actuation of the metered dose inhaler is about 55% to about 85%, and wherein said fine particles have a particle size of less than about 4.7μm.

9. (currently amended) The metered dose inhaler according to claim 8, wherein the percent of ~~the~~ fine particles dispensed upon actuation of the metered dose inhaler is about 65% to about 80%, and wherein said fine particles have a particle size of less than about 4.7μm.

10. (original) A process for producing an aerosol suspension formulation for inhalation, said aerosol suspension formulation for inhalation comprising:

an effective amount of mometasone furoate and a non-chlorofluorocarbon based propellant; wherein the formulation is free of a carrier, comprising the steps of:

a) mixing a dry powder blend of micronized mometasone with a dry powder surfactant to form a uniform mixture;

b) filling said mixture into a metered dose inhaler canister;

c) crimping said canister with a metering valve; and

d) filling said canister with a non-chlorofluorocarbon based propellant.

11. (original) The process according to claim 10, wherein the dry powder surfactant is selected from the group consisting of lecithin, stearic acid, palmitic acid, magnesium stearate, magnesium palmitate and magnesium laureate.

12. (original) The process according to claim 10, wherein the non-chlorofluorocarbon based propellant is HFA 227.

13. (original) The product produced by the process of claim 10.

14. (original) The product of claim 13, wherein the mometasone furoate is present in an amount of about 50 μg to about 400 μg.

15. (original) The product of claim 14, wherein the mometasone furoate is present in an amount of about 100 μg.

16. (original) The product of claim 14, wherein the mometasone furoate is present in an amount of about 200 μg.

17. (original) The product of claim 14, wherein the mometasone furoate is present in an amount of about 400 μg.

18. (original) The product of claim 13, wherein the formulation is free of additional excipients, and wherein the metered dose inhaler emits a dose having uniform drug content upon actuation of the metered dose inhaler.

19. (as amended) The product of claim 13, wherein the percent of ~~the~~ fine particles dispensed upon actuation of the metered dose inhaler is about 55% to about 85%, and wherein said fine particles have a particle size of less than about 4.7μm.

20. (as amended) The product of claim 19, wherein the percent of ~~the~~ fine particles dispensed upon actuation of the metered dose inhaler is about 65% to about 80%, and wherein said fine particles have a particle size of less than about 4.7μm.

REMARKS

Claims 1-20 are currently pending. Claims 1-20 stand rejected.

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Amendments to the Specification

The amendments to the specification on pages 3, 10 and 11 were made to correct typographical errors and in response to the objections raised in the Office Action to the specification. As an initial matter, Applicants respectfully point out that while the Office Action states that the correct in-line formula on page 3 of the specification should read "CF_3CHFCH_3", this formula is, in fact, incorrect. As would be understood by one skilled in the art, the correct in-line formula should read "CF_3CHFCF_3", and has been amended accordingly. Further, pages 10 and 11 have been amended by capitalization and notation of trademarks in order to clearly recognize the trademarks in accordance with the recommendation in the Office Action.

35 U.S.C. § 112;2d Rejections

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

With respect to claim 1 the Office Action objects to the use of the word "substantially", asserting that the term is not defined by the claim or the specification, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully disagree with the this contention that the specification does not provide a standard for ascertaining the requisite degree. In order to expedite prosecution of the instant application, however, Applicants have amended claim 1 to remove the word "substantially." In view of the presently amended claim, Applicants respectfully request reconsideration and withdrawal of this §112, second paragraph rejection.

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The Office Action also contends that the phrase "free of a carrier" is indefinite because the specification does not clearly "redefine" the term. Applicants respectfully disagree and traverse this rejection. As recently made clear by the Federal Circuit, the claims must be read in light the of the specification as it is the best single guide to the meaning of a disputed claim. Phillips v AWH Corp., 415 Fed.3d 1303 Fed. Cir.2005, cert denied 2006 US Lexus 1154 (Feb. 21, 2006) As taught by the specification at page 6

...

> As is known to one of skill in the art, a carrier and /or bulking agent is an inert substance in which or on to which the active drug ingredient(s) and excipeint(s) if present are dispersed. When the formulations of the present invention utilize HFA 227 as the propellant, it has been surprisingly found that a carrier is not necessary. Accordingly there is disclosed a metered dose inhaler containing an aerosol suspension formulation for inhalation, said aerosol suspension formulation for inhalation comprising: an efrective amount of mometasone furoate and HFA 227, wherein the formulation is substantially free of a carrier. The processes for producing the formulations of the present invention preferably utilize HFA 227 or HFA 134a, or a combination thereof, in combination with mometasone furoat and dry powder surfactant.

In light of the specification, it is unclear to the Applicants why the Office Action would conclude that the propellant of the instant invention, specifically HFA 227, is encompassed by the term "carrier". The specification clearly distinguishes the terms "propellant" and "carrier". The specification states at page 6, lines 12-13, "the propellant serves as a vehicle for both the active ingredients and excipients." The specification separately defines a carrier at page 6, line 23 to page 7, line 1 as "an inert substance in which or on to which the active drug ingredient(s) and excipient(s) if present are dispersed." The specification then goes on to distinguish HFA 227 from a carrier, stating on page 7, lines 1-3, that when the formulations of the present invention utilize HFA 227 as the propellant, a carrier is not necessary.

Further, even the PTO guidelines do not support the present rejection. M.P.E.P. §2173.02 clearly states that "the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available," and that the definiteness of claim language must be analyzed in light of "[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." Applicants submit that a worker skilled in the art would readily appreciate that HFA 227 is not a carrier as that term is used in the present application. Accordingly, a skilled worker would not regard the language "free of a carrier" as indefinite. Applicants therefore respectfully request reconsideration and withdrawal of this §112, second paragraph rejection.

Finally, claims 8, 9, 19 and 20 have been rejected because it is asserted that there is no antecedent bases for the phrase "the fine particles". These claims have been amended to address this issue. In light of the amendments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Applicants submit that claims 1-20 comply with the requirements of 35 U.S.C. § 112, second paragraph, and, therefore, respectfully request reconsideration and withdrawal of the rejections under §112, second paragraph.

35 U.S.C. § 103 Rejections

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759). The Office Action has alleged that it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place the compositions taught by Fassberg within a metered does inhaler

(MDI) to obtain the claimed products of the instant invention, because Fassberg teaches all of the components of the formulation contained within Applicants' claimed MDI, namely HFA 227, surfactant and mometasone furoate, and suggests that suspensions of the disclosed formulations are particularly preferred for MDI's.

As an initial matter, the Office Action has noted that the requirement that the formulation be free of a carrier was not given weight for examination purposes. As noted above, the specification makes it clear that HFA 227 is not, in fact a carrier (see page 7, lines 1-3) and distinguishes propellants from carriers. Further, one of ordinary skill in the art would know that HFA 227 is not a carrier as that term is used in the present application. For these reasons, Applicants respectfully submit that it is necessary to give weight to the requirement that the formulation be free of a carrier in distinguishing the instant invention from the prior art.

The Fassberg reference does not suggest, much less teach that the formulation disclosed therein be free of a carrier. Since there is no motivation for a skilled artisan to modify the method the Fassberg invention to create the claimed invention, the Fassberg invention does not make the claimed invention obvious or unpatentable. Accordingly, for the above cited reasons, Applicants respectfully request reconsideration and withdrawal of this § 103 rejection.

Further, claims 1-6, 8-17, and 19-20 stand rejected under § 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1). The Office Action has alleged that it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combined the teachings of Disckinson and Kaplan to obtain metered dose inhalers

containing a formulation comprising mometasone fluorate, HFA 227, and a surfactant. Applicants respectfully traverse the rejection.

The Office Action has combined the Dickinson reference with the Kaplan reference. The combination of Dickinson and Kaplan does not make obvious the instant invention because neither teaches an effective amount of mometasone fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier as is presently claimed. The primary reference (Dickinson) does not teach a formulation free of a carrier. The Office Action attempts to reach the instant invention by combining the Dickinson reference with the Kaplan reference to allege that claims 1-6, 8-17 and 19-20 are obvious. However, the Dickinson reference does not teach or suggest the claimed invention even with the Kaplan reference. The deficiencies of Dickinson, namely its failure to disclose a formulation free of a carrier, are not overcome by Kaplan since Kaplan also fails to disclose a formulation free of a carrier. Since there is no motivation for a skilled artisan to modify the method of Dickinson, with or without the Kaplan reference, to make the claimed invention these references do not make the claimed invention obvious or unpatentable.

Double Patenting Rejection

Claims 1-5, 7 and 13-18 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759. Applicants respectfully traverse the obvious-type double patenting rejection and submit that a prima facie case of obviousness has not been made.

The '759 patent is silent and does not claim the disclosed formulation free of a carrier. The Applicants, on the other hand, claim an effective amount of mometasone

fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier. As noted above, the specification makes it clear that HFA 227 is not, in fact a carrier (see page 7, lines 1-3) and distinguishes propellants from carriers. Further, one of ordinary skill in the art would know that HFA 227 is not a carrier as that term is used in the instant application. For these reasons, Applicants respectfully submit that it is necessary to give weight to the requirement that the formulation be free of a carrier in distinguishing the instant invention from the prior art.

It is well settled that the test for obvious type double patenting is whether any claim in the application merely defines an obvious variation of an invention disclosed and claimed in the patent. Disclosure of a prior patent may be used as a basis for an obvious type double patenting rejection only to the extent that it is claimed. When the differences between the two claimed inventions are not obvious, a second full-term patent is issued. The claims in the '759 patent do not teach or suggest what the Applicants claim. Specifically, the '759 patent does not literally claim an effective amount of mometasone fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier.

The Applicants contend that since the cited reference does not teach or suggest what the Applicants claim, a prima facie case of obviousness has not been made. Reconsideration and withdrawal of the rejection under obvious type double patenting is respectfully requested.

Claims 1, 2-5, and 13-17 also stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims

1, 2, 10 and 12 of copending Application No. 10/967,719 (copending '719) in view of Kaplan et al. (U.S. Patent Application US22202/0076382). Since the conflicting claims have not in fact been patented, this is a provisional statutory type double patenting rejection. Applicants respectfully traverse the this rejection.

The copending '719 claims an MDI having a metering valve containing an aerosol suspension formulation comprising a compound selected from the group consisting of mometasone furoate, mometasone furoate monohydrate, formoterol, formoterol fumarate, and/or any combination of any of the same; a suspension medium selected from the group consisting of 1,1,1,2,3,3,3-heptafluoropropane, 1,1,1,2-tetrafluoroethane; and a solvent that is ethanol. The copending '719 is silent and does not claim the disclosed formulation free of a carrier.

Kaplan does not compensate for this deficiency. The Office Action alleges that Kaplan teaches formulations of mometasone (preferably an ester of mometasone, including mometasone furoate) and a bronchodilator, including formoterol for pulmonary administration. Further the Office Action contends that Kaplan teaches that aerosol formulations of his invention may be administered via pressurized metered dose inhalers. However, Kaplan, like the '719 co-pending, fails to teach and does not claim the disclosed formulation free of a carrier. The Applicants, on the other hand, claim an effective amount of mometasone fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier.

As stated above the test for obvious type double patenting is whether any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent, or, in this case, a copending application. Disclosure of the prior application

may be used as a basis for an obvious type double patenting rejection only to the extent that it is claimed. When the differences between the two claimed inventions are not obvious, a second full-term patent is issued. Neither the claims in the '719 co-pending nor those in Kaplan teach or suggest what the Applicants claim. Specifically, neither the '719 co-pending nor Kaplan literally claims an effective amount of mometasone fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier.

The Applicants contend that since the cited references do not teach or suggest what the Applicants claim, a prima facie case of obviousness has not been made. Reconsideration and withdrawal of the rejection under obvious type double patenting is respectfully requested.

Finally, claims 1, 10 and 13 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 10/649,398 (copending '398). Since the conflicting claims have not in fact been patented, this is a provisional statutory type double patenting rejection. Applicants respectfully traverse the this rejection.

The Office Action maintains that, although the conflicting claims are not identical, they are not patentably distinct from one another because they are overlapping in scope. Applicants respectfully disagree. The copending '398 claims a process of introducing a suspension or solution of mometasone furoate anhydrous into a metered dose inhaler container, said container having a valve attached. Dependent claims 3 and 7 of the copending '398 further limit the propellant to the group consisting of HFA 227 and HFA 134a. And claims 2 and 6 are purported to be product by process claims treated as MDI products containing an aerosol formulation comprising mometasone furoate

anhydrous, a surfactant and a CFC free propellant. The copending '398 is silent and does not claim the disclosed formulation free of a carrier. The Applicants, on the other hand, claim an effective amount of mometasone fouroate (not mometasone furoate anhydrous as is claimed in the '398 copending) , a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier.

Applicants maintain that the differences between the instant invention and the invention claimed in the '398 copending are not obvious. The '398 copending does not teach or suggest what the Applicants claim. Specifically, the '398 does not literally claims an effective amount of mometasone fouroate, a dry powder surfactant and HFA 227, wherein the formulation is free of a carrier. Neither is the scope of these claims co-extensive with the scope of the claims of the instant application.

The Applicants contend that since the cited reference does not teach or suggest what the Applicants claim, a prima facie case of obviousness has not been made. Reconsideration and withdrawal of the rejection under obvious type double patenting is respectfully requested.

Information Disclosure Statement

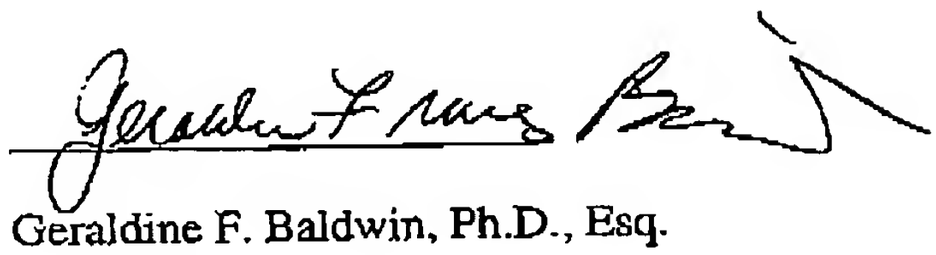
Applicants note that the Office Action indicates that the copending application – 10/229,855- referred to in the Information Disclosure Statement filed on October 14, 2003 was not considered, because said copending application was abandoned on May 5, 2005. However, this application was abandoned in favor of U.S. Patent Application U.S. Serial No. 11/071078, currently pending. Submitted herewith is a new Information Disclosure Statement which directs the Office's attention to the existence of

co-pending U.S. Patent Application U.S. Serial No. 11/071078, filed March 3, 2005, currently before Examiner Kim of Art Unit 1617.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of claims and submit that all pending claims are in form for allowance.

Respectfully submitted,



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